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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,791	03/14/2002	Marja Heiskala	CEN 0285-NP	3070

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,791	HEISKALA, MARJA	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-55 are pending in the application and are currently under prosecution.

Claim 55 is a linking claim, linking groups 1-6.

The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 55 . Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 1-5, 7, 15-17, 25-36, 39-44, 50, 52-55, drawn to a human Ig derived protein, or a portion or variant thereof, that binds to at least one epitope comprising the entire amino acid sequence of SEQ ID NO:2, or a fragment thereof of SEQ ID NO:4-11, classified in class 530, subclass 387.1.

Group 2. Claims 6, 8-13, 55, drawn to a nucleic acid encoding the human Ig derived protein, or a portion or variant thereof, a vector, a host cell, classified in class 536, subclass 23.1.

Group 3. Claims 14, 45-48, 55, drawn to an in vitro or in vivo method for producing at least one human Ig derived protein, or a portion or variant thereof, classified in class 435, subclass 70.1.

Group 4. Claims 18-24, 37-38, 51, 55, drawn to a method for treating a malignant condition or a disease condition, comprising administering at least one human Ig derived protein, or a portion or variant thereof, classified in class 424, subclass 130.1.

Claim 49 is a linking claims, linking groups 5-6.

The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 55 . Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 5. Claim 49, 55, drawn to a transgenic animal expressing at least one human Ig derived protein, or a portion or variant thereof, classified in class 800, subclass 2.

Group 6. Claim 49, 55, drawn to a transgenic animal or plant expressing at least one human Ig derived protein, or a portion or variant thereof, classified in class 800, subclasse 200.

Groups 1-6 are further subject to election of a single disclosed species.

Claims 1-55 are generic to a plurality of disclosed patentably distinct species comprising a human Ig derived protein that binds to the full length amino acid sequence of SEQ ID NO:2, or a fragment thereof of SEQ ID NO: 4-11, wherein SEQ ID NO:2 is generic to SEQ ID NO: 4-11.

The inventions are distinct, each from the other because of the following reasons.

Inventions 1, 2, 5-6 are patentably distinct products.

The polypeptide of group 1 and polynucleotide of group 2 are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, while a polypeptide of group 1 can made by methods using some, but not all, of the polynucleotides that fall within the scope of group 2, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the

inventions of groups 1 and 2 are patentably distinct.

Furthermore, searching the inventions of groups 1 and 2 together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups 1 and 2 have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups 1 and 2 together.

The polypeptide of group 1 and the transgenic animal or plant of groups 5-6 are patentably distinct inventions for the following reasons. The polypeptides of group 1 are composed of amino acids, and encompasses human antibodies or fragments thereof which comprises heavy and/or light chains containing constant and variable regions. The transgenic animal or plant is composed of a complex of cells, tissues and/or organs. In addition, while a polypeptide of group 1 can made by methods using the transgenic animal or plant that fall within the scope of groups 5-6, it can also be recovered from a different source. For instance, the human Ig derived polypeptide could be produced by bacteria or hybridoma, and isolated using affinity

chromatography. For these reasons, the inventions of groups 1 and 5-6 are patentably distinct.

Furthermore, searching the inventions of groups 1 and 5-6 together would impose a serious search burden. In the instant case, the search of the polypeptides and the transgenic animal or plant are not coextensive. The inventions of Groups 1 and 5-6 have a separate status in the art as shown by their different classifications. Searching for the epitopes of the human Ig derived protein of group 1 would not be necessarily required for the search of the transgenic animal or plant that expresses the human Ig derived protein of group 1. As such, it would be burdensome to search the inventions of groups 1 and 5-6 together.

The polynucleotide of group 2 and the transgenic animal or plant of groups 5-6 are patentably distinct inventions for the following reasons. The polynucleotides are composed of purine and pyrimidine units, whereas the transgenic animal or plant is composed of a complex of cells, tissues and/or organs. In addition, the polynucleotides can be made by a plasmid replicated in bacteria, or by polymerase chain reaction, whereas the transgenic animal or plant can be made by an entirely different process, for example, by introducing a vector comprising the polynucleotides into a host animal or plant.

Furthermore, searching the inventions of groups 2 and 5-6 together would impose a serious search burden. In the instant case, the search of the polynucleotides and the transgenic animal or plant are not coextensive. The inventions of Groups 2 and 5-6 have a separate status in the art as shown by their different classifications.

Searching for the structural sequence of the polynucleotide group 2, for example the structure of the light chain sequence encoding the complementary determining region, would not be necessarily required for the search of the transgenic animal or plant that expresses the entire human Ig derived protein of group 2. As such, it would be burdensome to search the inventions of groups 1 and 5-6 together.

The transgenic animal of group 5 and the transgenic plant of group 6 are patentably distinct inventions for the following reasons. The transgenic animal is composed of organs and has immunological reactions that could suppress the production of the polypeptide, which are not found in plant. In addition, while the polypeptide can be made in plant, the polypeptide may not be necessarily made in certain transgenic animals.

Furthermore, searching the inventions of groups 5-6 together would impose a serious search burden. In the instant case, the searches of the transgenic animal or plant are not coextensive. The inventions of Groups 5-6 have a separate status in the art as shown by their different classifications. Searching for the transgenic animal would not be required for the search of the transgenic plant that expresses the human Ig derived protein . As such, it would be burdensome to search the inventions of groups 5-6 together.

Inventions 3-4 are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different objectives, modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant

specification does not disclose that these methods would be used together. The method of treating cancer or diseases of group 2 using the polypeptide and the method of producing the human Ig derived protein using the polynucleotide are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs its function using a structurally and functionally divergent material. For treatment of cancer or a disease using the polypeptide, the polypeptide is administered to a patient having cancer or disease, using any mode of administration. For producing the human Ig derived protein, expression of nucleic acid encoding the polyppetide in in vitro or in vivo host cells is required. Therefore, each method is divergent in materials and steps. For these reasons the Inventions 3-4 are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups 3-4 have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups 3-4 together.

Inventions 1 and 4 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of group 1 can be used to make affinity columns as opposed to its use in treating a disease.

Searching the inventions of Groups 1 and 4 together would impose serious search burden. The inventions of Groups 1 and 4 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treating a disease using a polypeptide are not coextensive. The search for group 4 would require a text search for the method of treating diseases in addition to structural search of the polypeptide. Prior art which teaches an epitope of the polypeptide of group 1 would not necessarily be applicable to the method of using the polypeptide of group 4. Moreover, even if the polypeptide product were known, the method of treating diseases using the product may be novel and unobvious in view of the preamble or active steps.

Inventions 1 and 3 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide product can be made by isolation of a natural source that has autoantibody to the polypeptide.

Searching the inventions of Groups 1 and 3 together would impose serious search burden. The inventions of Groups 1 and 3 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the in vivo method of producing the polypeptide are not coextensive. The search for group 3 would require a text search for the in vivo method of producing the polypeptide, in addition to structural search of the polypeptide. Prior

art which teaches an epitope of the polypeptide of group 1 would not necessarily be applicable to the method of using the polypeptide of group 3. Moreover, even if the polypeptide product were known, the in vivo method of making the product may be novel and unobvious in view of the preamble or active steps.

Inventions 2 and 3 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group 2 can be used to diagnosing a disease as opposed to its use in making the polypeptide.

Searching the inventions of Groups 2 and 3 together would impose serious search burden. The inventions of Groups 2 and 3 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of making the polypeptide in vivo using a polynucleotide are not coextensive. The search for group 3 would require a text search for the method of making the polypeptide in vivo in addition to structural search of the polynucleotide. Prior art which teaches the polynucleotide of group 1 would not necessarily be applicable to the method of using the polynucleotide of group 3. Moreover, even if the polypeptide product were known, the method of treating diseases using the product may be novel and unobvious in view of the preamble or active steps.

Inventions 3 and 5-6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic animal or plant of groups 5-6 can be used to testing the effect of drugs on the expression of the polynucleotide in the transgenic animal or plant as opposed to its use in making the polypeptide.

Searching the inventions of Groups 3 and 5-6 together would impose serious search burden. The inventions of Groups 3 and 5-6 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the transgenic animal or plant and the method of making the polypeptide are not coextensive. Prior art which teaches the transgenic animal or plant of groups 5-6 would not necessarily be applicable to the method of producing the polypeptide, for example, by bacteria or cell in culture of group 3.

Inventions 2 and 4, 5-6 are unrelated because the product of group 2, 5 or 6 is not used or otherwise involved in the process of group 4.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

October 18, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER